

REMARKS

Claims 1, 3 and 7-17 are currently pending in the subject patent application and are currently under consideration. Claims 1, 10 and 13 have been amended herein to expedite allowance of the subject patent application. Support for the amendments to claims 1, 10 and 13 can be found at, for example, at page 4, line 22 – page 5, line 7 of the instant specification. Favorable reconsideration is respectfully requested in view of the comments and amendments herein.

I. Rejection of Claims 1, 3 and 7-17 Under 35 U.S.C. §112

Claims 1, 3 and 7-17 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Independent claims 1, 10 and 13 have been amended herein in accordance with the Examiner's suggestions in the Office Action. In addition, applicants' representative respectfully disagrees with the Examiner's assertion that the combination of inserting one or more constructs and using a second construct to close the opening lacks original support. At page 4, line 22 – page 5, line 7, the instant specification recites "...depending on the size of the patient and the size of the hole in the annulus, one or more pieces may be used to plug the hole...optionally and additionally, a cultured connective tissue construct is applied over the opening...". Therefore, the claimed combination is adequately supported by the instant specification. Accordingly, this rejection should be withdrawn.

II. Rejection of Claims 1, 3 and 7-17 Under 35 U.S.C. §103(a)

Claims 1, 3 and 7-17 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Stovall (WO 99/04720) in view of Murphy *et al.* (WO 00/29553) and further in view of Lambrecht *et al.* (US 7,220,281). Applicant's representative respectfully requests that this rejection be withdrawn for at least the following reasons. The cited references, either alone or in combination, fail to teach or suggest all aspects set forth in the subject claims.

To reject claims in an application under §103, an examiner must establish a *prima facie* case of obviousness. A *prima facie* case of obviousness is established by a showing of three basic criteria. First, there must be some suggestion or motivation, either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second there must be a reasonable expectation of success. *Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See MPEP §706.02(j).* The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art and not based on the Applicant's disclosure. *See In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added).

The claimed invention relates to uses of cultured living connective tissue constructs in surgical repair indications. In particular, amended independent claim 1 recites a method for repairing an intervertebral disc of a patient using a cultured connective tissue construct, comprising: forming at least one opening in the annulus fibrosis of the intervertebral disc; removing at least a portion of the nucleus pulposus through the opening in the annulus fibrosis; inserting one or more cultured connective tissue constructs into the opening of the annulus fibrosis; and subsequently grafting an additional connective tissue constructs to close the opening with the one or more cultured connective tissue construct in the annulus fibrosis, wherein the cultured connective tissue constructs comprise: an extracellular matrix layer; and cultured fibroblast cells that synthesize and assemble the layer of extracellular matrix in the absence of exogenous matrix components or synthetic members. Amended independent claims 10 and 13 recite similar aspects. Stovall, Murphy *et al.* and Lambrecht *et al.* do not teach or suggest such aspects of the subject claims.

Stovall relates to treating ruptured intervertebral discs by employing polymer solutions, cells or a combination thereof in liquid form. Stovall further allows for the polymer solution, with or without chondrocytes or fibroblasts, to be injected or applied upon or within the annular fibrosis in liquid form through an overlaying scaffold. Since Stovall uses a combination of a liquid chondrocyte suspension in conjunction with a separate scaffold, Stovall requires first covering the hole, then subsequent injection of the liquid suspension through the overlaying scaffold. To the contrary, the claimed invention requires the initial insertion of one or more cultured constructs into the opening of the annulus fibrosis, followed by a subsequent overlaying cultured construct to close the opening. Moreover, the teachings of Murphy *et al.* do not render the claimed invention obvious, since the Examiner relies on Murphy *et al.* to show that

constructs without exogenous support materials can be used. In other words, Stovall and Murphy *et al.*, either alone or in combination, do not teach or suggest the specific process of inserting one or more cultured connective tissue constructs into the opening of the annulus fibrosis; and subsequently grafting an additional connective tissue construct to close the opening with the one or more cultured connective tissue constructs in the annulus fibrosis, as claimed.

With regard to Lambrecht *et al.*, in view of the amendments to independent claims 1, 10 and 13, the Examiner's new matter rejection is now moot. Therefore, since the filing date of the instant patent application precedes the filing date of Lambrecht *et al.*, the cited reference has been improperly applied for this rejection.

In view of at least the foregoing, it is readily apparent that the cited references, either alone or in combination, do not teach or suggest all aspects of the subject claims. Accordingly, this rejection should be withdrawn.

CONCLUSION

The present application is believed to be in condition for allowance in view of the above comments and amendments. A prompt action to such end is earnestly solicited.

In the event any additional fees are due in connection with this document, the Examiner is invited to contact applicant's undersigned representative at the telephone number below.

Respectfully submitted,

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